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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,294	12/19/2001	Suzie Hwang Pun	CTCH-P014	9341
28120	7590	08/17/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 08/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,294

Applicant(s)

PUN ET AL.

Examiner

Leigh C. Maier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7, 11-18 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7, 11-18, 22-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 5, 15-17, 20, and 21 have been amended. Claims 22-28 are newly submitted. Claims 5-7, 11-18, and 20-28 are pending. Claims 20 and 21 remain withdrawn from consideration at this time. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7, 11-18, 21, 22, 24, 25, 27, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

Claim 5 has been amended to require that “the complexing agent comprises at least one polymer portion.” Applicant cites page 41, line 2 as support for this limitation. The passage in the specification states that the “complexing agent may also be functionalized with polymers that increase solubility and/or impart stabilization, particularly under biological conditions.” The

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generic limitation requiring a “polymeric portion” is broader than what is described in the specification. With respect to solubility, of course, it could be argued that any “polymeric portion” is going to increase solubility, depending on the solvent. However, it does not appear that Applicant has identified a utility that requires other than an aqueous environment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation “the side chains” in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

Claims 5-7, 12-18, and 22-27 are rejected under 35 U.S.C. 102(e) as being anticipated by WOLFF et al (US 6,740,643).

The claims have been amended to require that “the complexing agent comprises at least one polymer portion.”

WOLFF discloses several compositions comprising a cyclodextrin-containing polymer, plasmid DNA and a complexing agent, as discussed in the previous Office action. Example 6 comprises a composition including a polymer containing cyclodextrins in the side chains, plasmid DNA and Triton-X 100 (a PEG ether of octylphenol).

Claim Rejections - 35 USC § 103

Claims 5-7, 12-18, and 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WOLFF et al (US 6,740,643).

WOLFF teaches as set forth above. The reference further teaches that a cyclodextrin-containing polymer in combination with an amphiphilic compound results in drug delivery system that may be employed generically for biologically active compounds, such as pharmaceuticals, peptides/proteins, viruses, etc. See col 17, lines 50-52 and col 18, lines 32-47. The reference does not exemplify any other biologically active compounds other than polynucleotides. Neither does the reference exemplify a polymeric complexing with a linear CD-polymer, although such polymers are exemplified in other example compositions.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute any of the biologically active compounds recited in claim 6 because these agents were expressly suggested by the reference. One of ordinary skill would reasonably expect success in making such a substitution because the reference had taught that this drug delivery system is a general one for biologically active compounds. It would further be within the scope of the artisan to select any of the exemplified CD-polymers to prepare the composition.

Double Patenting

Claims 5-7 and 11-21 are again provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-20 of

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compending Application No. 10/021,312, as set forth in a previous Office action. Applicant has indicated a willingness to submit a terminal disclaimer, if necessary, upon notice of allowability.

Allowable Subject Matter

Claim 11 is objected to as being dependent upon a rejected base claim (insofar as it requires a “guest” on the complexing agent), but would be allowable if rewritten (with appropriate amendment to obviate new matter rejection) in independent form including all of the limitations of the base claim and any intervening claims. WOLFF teaches a complexing agent comprising a PEG component, as set forth above. The art does not provide any motivation to prepare complexing agents having PEG linkers with the guest molecules recited in claim 11.

Allowable subject matter was indicated in a previous Office action. Upon further review of WOLFF, the scope of allowable subject matter is amended as follows:

1. a CD-containing polymer;
2. a therapeutic agent; and
3. guest*—PEG (optionally including branching and additional linkers)—functional group.

*As noted previously, “therapeutic agent” and “functional group” are generic. The scope of the guest would be limited to those discussed above.

Applicant’s amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov> Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
August 15, 2005